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In the Supreme Court of the United States

CUOZZO SPEED TECHNOLOGIES, LLC,
Petitioner,

v.

MICHELLE K. LEE, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR, PATENT AND TRADEMARK OFFICE,
Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR AARP AS AMICUS CURIAE SUPPORTING RESPONDENT

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INTEREST OF AMICUS CURIAE[1]

AARP is a nonpartisan, nonprofit membership organization dedicated to addressing the needs and interests of people age fifty and older. AARP advocates for access to affordable healthcare and for controlling costs without compromising quality. Access to affordable healthcare is particularly important to the older population, which has higher rates of chronic and serious health conditions. Patents that have been improperly granted have a direct impact on the cost of prescription drugs. In light of the impact the cost of drugs has on the accessibility of healthcare, AARP's Public Policy Institute has been tracking the cost of widely used prescription drugs since 2004, and publishes the *Rx Price Watch* series reporting on changes in the cost of drugs widely used by older Americans.[2]

Through its charitable affiliate, AARP Foundation, AARP has previously served as amicus in other patent cases. *E.g., Nautilus Inc. v. Biosig*

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[1] In accordance with Supreme Court Rule 37.6. AARP states that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than AARP, its members and its counsel have made a monetary contribution to the preparation or submission of this brief. Consent of the parties has been obtained. Petitioner filed a blanket consent with the Court, and the Respondent has given written consent, which will be filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

[2] The 2010-2016 editions are *available at* http://bit.ly/1yXUYDN.

Instruments, Inc., 134 S. Ct. 2120 (2014); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Bilski v. Kappos*, 561 U.S. 593 (2010).

This Court's decision, which will determine the claim-construction rule used at the United States Patent and Trademark Office (PTO), will impact the ability of interested parties to challenge questionable patents. In light of the significance of the issue presented in this case, AARP respectfully submits this amicus curiae brief to address the first question presented to the Court: whether the Patent Trial and Appeal Board may construe patent claims according to their broadest reasonable interpretation.

SUMMARY OF THE ARGUMENT

Congress designed the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011), to overturn patents that should have never been issued in the first place. The current *inter partes* review (IPR) system is working as intended, and patents that should have never been issued are being invalidated. The Federal Circuit correctly held that the United States Patent and Trademark Office (PTO), in adopting 37 C.F.R. 42.100(b), acted within its rulemaking authority. which consistent with the agency's settled practice in other post-issuance proceedings provides that patent claims shall be given their "broadest reasonable construction" during *inter partes* review proceedings.

When patents are improperly issued they undermine competition, increase healthcare and other consumer costs, with no offsetting benefit to consumers. The public has a "paramount interest in seeing that patent monopolies are kept within their legitimate scope." *Medtronic, Inc. v. Mirowski Family Ventures, L.L.C.*, 134 S. Ct. 843, 851 (2014). As a result of the monopolies created by drug patents, health care consumers have paid ever-increasing prices for prescription medications. AARP's research indicates that between 2006 and 2013, retail prices for 140 brand-name drugs used by many older adults increased by an average of 113 percent. Stephen W. Shondelmeyer and Leigh Purvis, *AARP: Rx Price Watch Report* 1 (2014).[3] Low-quality patents have a direct impact on the cost of pharmaceutical drugs, to the detriment of older individuals and the public, generally. The Court should affirm the judgment of the Federal Circuit.

ARGUMENT

I. CONGRESS CREATED *INTER PARTES* REVIEW TO IMPROVE PATENT QUALITY AND GAVE THE PTO FULL AUTHORITY TO SET THE APPROPRIATE CLAIM CONSTRUCTION STANDARD.

The Leahy-Smith America Invents Act (AIA) Pub. L. No. 112-29, 125 Stat. 284 (2011) was

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[3] *Available at* http://www.aarp.org/content/dam/aarp/ppi/2014-11/rx-price-watch-report-AARP-ppi-health.pdf.

designed to get rid of patents that should not have been issued in the first place. One of the bill's authors noted that one of the purposes of the act was "to correct egregious errors" made by the PTO in granting patents. 157 CONG. REC. S7413 (daily ed. Nov. 14, 2011) (statement of Sen. Kyl) (reading into the Record a letter from Lamar Smith, Chairman of the House Judiciary Committee). As Sen. Smith noted: "The strength of our patent system relies on not simply the mechanical granting of a patent, but the granting of strong patents, ones that are truly novel and non-obvious inventions, that are true innovations and not the product of legal gamesmanship." *Id.* Through the AIA, Congress sought to provide "a meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court." H.R. Rep. No. 112-98 pt. 1, at 48 (2011) (*House Report*).

The AIA instructs the PTO to "prescribe regulations establishing and governing inter partes review." 35 U.S.C. § 316(a)(4). Exercising that authority, the PTO adopted the broadest reasonable claim interpretation standard. 37 C.F.R. § 42.100. That standard has been employed by the PTO in a variety of contexts for a century, and, as the Federal Circuit noted, "[t]here is no indication that the AIA was designed to change the claim construction standard that the PTO has applied for more than 100 years." *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1277 (Fed. Cir. 2015).

A. The Presumption That an Issued Patent is Valid Does Not Apply to Agency Decisions.

In district court patent infringement litigation, there is a statutory presumption that an issued patent is valid. 35 U.S.C. § 282. That presumption, however, does not apply in IPR proceedings where, unpatentability needs to be proved by a preponderance of evidence. *See* Resp. Br. 6-7; 19-20. Unlike district court litigation, patent claims can still be amended or replaced during PTO administrative proceedings. *Id.*; 35 U.S.C § 316 (e). The IPR process can only be instituted when "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C § 314; 324. Given the high standard to even institute IPR, and the "reasonable likelihood" that at least one of the patent claims is invalid it makes sense that the presumption of validity does not apply in IPR proceedings.

As this Court has previously noted, the presumption of patent validity is greatly diminished when patent examiners have not considered the prior art. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 426 (2007). The United State Patent and Trademark office's initial determinations granting patents "...are reached under tight time constraints and on an *ex parte* basis allowing minimal opportunity to hear a third party's opposing views." Fed. Trade Comm, *To Promote Innovation. The Proper Balance of Competition and Patent Law and Policy*, 28 (Oct. 2003), http://1.usa.gov/1d7fQwQ. As the Federal Trade Commission observed given "all the failings of

ex parte examination" there is a compelling case against imposing a heightened evidentiary standard on parties who challenge patent validity. *Id.*; *see also* Doug Lichtman & Mark Lemley. *Rethinking Patent Law's Presumption of Validity*, 60 Stan. L. Rev. 45 (2007) (noting that given the high volume of patent applications "it is hardly a surprise that the PTO makes mistakes during the initial process of patent review, granting patents that, on the merits, should never have been issued. The real surprise is that the law makes issuance mistakes hard to reverse.").

II. PATENT CLAIMS THAT DO NOT MEET THE BROADEST REASONABLE INTERPRETATION STANDARD SHOULD BE INVALIDATED.

Patent claims "are required to be cast in clear—as opposed to ambiguous, vague, indefinite — terms. It is the claims that notify the public of what is within the protections of the patent, and what is not." *In re Packard*, 751 F.3d 1307, 1313 (Fed. Cir. 2014) (*citing United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236); *see also Nautilus*, 134 S. Ct. at 2129) (holding that a patent must be precise enough to afford clear notice of what is claimed to inform those skilled in the art about the scope of the invention with reasonable clarity). The Patent Act mandates that patent specifications be written using "full, clear, concise and exact terms." 35 U.S.C. § 112(a). The patent specification must particularly point out and "distinctly" claim the subject matter that the inventor regards as the invention. 35 U.S.C. § 112(b).

The public has a "paramount interest in seeing that patent monopolies are kept within their legitimate scope." *Medtronic, Inc.*, 134 S. Ct. at 851 As this Court noted in *Precision Instrument Mfg. Co.*,

> [a] patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts.' At the same time, a patent is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.

324 U.S. at 816.

The broadest reasonable interpretation (BRI) standard "serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified." *In Re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984). As the PTO notes in its Patent Trial Guide, the BRI approach ensures that the public can clearly understand the outer limits that applicants and patentees will attribute to their claims. Additionally, although the IPR process is still new, the AIA contemplates that:

> [T]here may be multiple proceedings involving related patents or patent applications in the Office at a particular time. For example, there may be an IPR of a patent that is also subject to an ex parte reexamination, where the patent is part of a family of co-pending applications all employing the same claim terminology. The Office applies the broadest reasonable interpretation standard in those proceedings, and major difficulties would arise where the Office is handling multiple proceedings with different applicable claim construction standards.

Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48764 (Aug. 14 2012)[4]; *see also* Resp. Br. 42.

As the PTO further explains,

> Only through the use of the broadest reasonable claim interpretation standard can the Office ensure that uncertainties of claim scope are removed or clarified. Since patent owners have the opportunity to amend their claims during IPR, PGR [Post Grant Review], and CBM [Covered Business Method] trials, unlike in district court proceedings, they are able to resolve ambiguities and

[4] *Available at* USPTO website, 1.usa.gov/1RsuRQj.

> overbreadth through this interpretive approach, producing clear and defensible patents at the lowest cost point in the system.

Id.

Petitioner and its amici urge this Court to force the PTO to adopt the claim construction standard described in *Phillips v. AWH Corp.*, 415 F.3d 1303. The *Phillips* standard, however, continues to create confusion. *See, e.g.*, Dan L. Burk and Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Claim Construction* 157 U. Pa. L. Rev. 1743, 1744-45 ("Despite repeated efforts to set out the rules for construing patent claims, culminating in the Federal Circuit's en banc *Phillips* decision in 2005, parties and courts seem unable to agree on what particular patent claims mean Literally every case involves a fight over the meaning of multiple terms, and not just the complex technical ones. Recent Federal Circuit cases have had to decide plausible disagreements over the meanings of the words 'a', 'or,' 'to,' 'including,' and 'through,' to name but a few ") (footnotes omitted).

Despite professing to give patent claims their "ordinary and customary" meaning, the *Phillips* standard upholds patent claims that redefine words and reject the ordinary meaning of words. Claim construction under *Phillips* specifically permits claim terms to have "a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess." *Phillips*, 415 F.3d at 1316.

What has been described as the "fractured nature of claim construction" after *Phillips* has caused some scholars and judges to urge courts to adopt the PTO's claim construction standard instead of the *Phillips* claim construction standard. *See, e.g.*, Andrew B. Dzeguze, *Did Markman and Phillips Answer the Right Question? A Review of the Fractured State of Claim Construction Law and the Potential Use of Equity to Unify It*, 15 Tex. Intell. Prop. L.J. 457, 482-489 (2007) (noting that post-*Phillips* claim construction is as fractured as ever; and proposing that district courts use the broadest reasonable interpretation rather than *Phillips)*; *Enzo Biochem, Inc. v. Applera Corp*, 605 F.3d 1347, 1348-1349 (Fed. Cir. 2010) (Plager J., dissenting from denial of panel rehearing) (noting the differences of approach between the PTO and the courts, and urging the Federal Circuit to "move in th[e] direction" of the PTO). Regardless of which standard would be preferable in district courts, Congress in enacting the AIA was well aware that the broadest reasonable interpretation standard was the prevailing rule at the PTO. *See* 157 CONG. REC. S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl). As the Federal Circuit held, "It can therefore be inferred that Congress impliedly approved the existing rule of adopting the broadest reasonable construction." *In re Cuozzo Speed Technologies, LLC*, 793 F.3d at 1277 Consistent with the BRI standard, the PTO can find claims to be indefinite "whenever reasonable alternative constructions are found to exist, requiring *applicants* to resolve the discovered ambiguities." Joshua D. Sarnoff & Edward D. Manzo, An Introduction to, Premises of, and Problems with Patent Claim Construction § 0:5 n.17 in *Patent Claim*

Construction In The Federal Circuit (Edward D. Manzo ed. 2016) (emphasis in original); ***Ex Parte Kenichi Miyazaki,*** No. 2007-3300,89 U.S.P.Q.2d 1207 (B.P.A.I. Nov 19, 2008) ("we hold that if a claim is amenable to two or more plausible claim constructions, the USPTO is justified in requiring the applicant to more precisely define the metes and bounds of the claimed invention"). As Judge Dyk explained in his opinion concurring in the denial of rehearing en banc, there are bills pending in Congress to change the IPR claim construction standard. If the claim construction standard is to be changed, it should be done by Congress, not the Court. Pet. App. 52a & n.1.

III. DUBIOUS PATENTS INCREASE HEALTHCARE COSTS AND BLOCK BIOMEDICAL RESEARCH.

Congress passed the AIA to "improve patent quality" and address a growing concern that the costs of patent litigation were negatively affecting the climate for investment and innovation. *House Report* 40, 48. The cost of litigating patent claims that result from poor patent quality is exceedingly high to both businesses and consumers. *See* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 Fed. Circuit B.J. 539, 600 (noting that the cost of litigating a dubious patent can be millions of dollars, and that " it is often prohibitively expensive or even impossible to test the validity of a newly-issued patent that is of dubious validity, and the continued existence of a patent can disrupt

product development in a field of technology for years.").

The Federal Circuit itself has noted that when patents are improperly granted, " competition in the marketplace is foreclosed and the public is forced to pay higher prices." *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368 (Fed. Cir. 2003) (quoting the District Court's opinion, *McNeil-PPC, Inc. v. L. Perrigo Co.*, 207 F Supp. 2d 356, 375 (E.D. Pa. 2002)). Unfortunately, the costs of patent litigation "are inevitably passed onto consumers, regardless of the outcome of the case." Brianna Lennon, *Antitrust Implications of Technology Patents*, 1 ABA Young Lawyer Div Antitrust Law Comm. Newsl. 8, 9 (2012), http://bit.ly/1fej47A.

Furthermore, improperly granted patents increase the cost of healthcare to the detriment of older people and the public, generally. AARP's most recent Public Policy Institute report analyzed the price changes in 622 commonly used drugs and found that: "[t]he average annual cost of [prescription drug] therapy was more than $11,000 per drug per year for widely used prescription drugs at the end-payer (retail) level in 2013." Stephen W Shondelmeyer & Leigh Purvis, *AARP: Rx Price Watch Report Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2006-2013* 6 (Feb.2016), http://bit.ly/1yXUYDN. The $11,000 average annual cost is almost half of the median income for Medicare beneficiaries ($23,500) and almost three-quarters of the average Social Security retirement benefit ($15,526). *Id.*, *see also* Jan

Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Aff. 219, 226 (2000), *available at* http://bit.ly/1l371My (noting that high cost of prescription drugs have compelled many older Americans to forgo needed drug treatment).

Prescription drug increases also affect employers, private insurers, and taxpayer-funded programs like Medicare and Medicaid. Generic drugs, available once a patent expires, or is found to be invalid, play a crucial role in containing rising prescription drug costs by offering consumers therapeutically identical alternatives to brand drugs at significantly reduced costs. The Generic Pharmaceutical Association reports that in 2014 alone "[g]eneric drugs were responsible for $254 billion in health system savings bringing the total savings over the last 10 years to $1.68 trillion. Generic Pharm. Ass'n, Generic Drug Savings in the U.S. 1 (7th ed. 2015), http://bit.ly/1Np0dGM.

Invalid patent claims not only impact the price of drugs, but can also block biomedical research. *See, e.g.*, Mildred K. Cho et al., *Effects Of Patents And Licenses On The Provision Of Clinical Genetic Testing Services*, 5 J. Molecular Diagnostics 3, 7 (2003), *available at* http://1.usa.gov/1bqUNKz (noting that more than half of laboratory directors had decided not to develop or perform tests specifically because of intellectual property considerations). The mere "knowledge that a patent application has been filed can influence the decision to spend the time and resources to develop a clinical test because of the

uncertain risk that a patent holder will later prevent the laboratory from continuing to provide this service." Jon F. Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine*, 45 Clinical Chemistry 324, 327 (1999), *available at* http://bit.ly/1gmvaYJ. Such concerns motivated Congress to pass the AIA and authorize the PTO to prescribe regulations establishing and governing IPR review. 35 U.S.C. § 316(a). Patent claims that do not meet BRI standard should be invalidated.

CONCLUSION

For the foregoing reasons, the Federal Circuit's judgment should be affirmed.

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